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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/830,751	09/10/2002	Patrick F Suthers	960296.96617	2012
26734	7590	01/09/2004	EXAMINER	
QUARLES & BRADY LLP FIRSTAR PLAZA, ONE SOUTH PINCKNEY STREET P.O. BOX 2113 SUITE 600 MADISON, WI 53701-2113			SAIDHA, TEKCHAND	
		ART UNIT	PAPER NUMBER	
		1652		

DATE MAILED: 01/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/830,751	SUTHERS ET AL.
	Examiner	Art Unit
	Tekchand Saidha	1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 24 January 2003.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) 7 is/are allowed.
- 6) Claim(s) 1-3,6 and 8-10 is/are rejected.
- 7) Claim(s) 4,5,11 and 12 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
 a) The translation of the foreign language provisional application has been received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) Interview Summary (PTO-413) Paper No(s) _____
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____

DETAILED ACTION

1. Applicant's sequence listing filed 01.24.2003 is acknowledged. Claims 1-12 are pending and under consideration in this application.

2. ***Specification***

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 112 (first paragraph)

3. ***35 U.S.C. § 112, first paragraph (Written Description)***

Claims 1-3, 6, & 8-10 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Claims 1-3, 6, & 8-10 are drawn to a method for producing 3-hydroxypropionic acid using recombinant microorganism expressing non-native enzymes (no name or structure) capable of catalyzing the production of 3-hydroxypropionic acid (3-HP) (claim 1), or microorganism expressing glycerol dehydratase and/or aldehyde dehydrogenase from any source (claims 2-3, 6, & 8-10). However, description to any such constructs is lacking.

The specification, however, only provides examples of microorganism (*E. coli*) transformed with expression of genes comprising (*dhaB* (glycerol dehydratase from *Klebsiella pneumoniae*); and any one of aldehyde dehydrogenase genes - *ALDH4*

(human) or *ALD2* (*S. cerevisiae*) or *aldA* (*E. coli*) or *aldB* (*E. coli*) and capable of producing 3-HP. There is no particular structure to function/activity relationship in the 4 possible combinations that can be obtained by using one of the 4 aldehyde dehydrogenases with glycerol dehydratase from *Klebsiella pneumoniae* (*dhaB*). From the disclosed species combinations it would be highly unlikely that one skilled in the art can isolate and establish similar combinations of the two genes (encoding aldehyde dehydrogenase and glycerol dehydratase) from any source, such as animal, plants, or microorganism among others, in order to obtain such a vast array of these undescribed genes (some yet undiscovered) and use it in a method for producing 3-HP, knowing that 3-HP has been described as an 'unstable chemical' [see USP 6,329,183 B2, column 3, lines 61-62]. Further, Applicants have provided no data regarding the accumulation of 3-HP during fermentation of these reconstructs.

Thus, Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention. Therefore, the written description requirement is not satisfied.

4. Claims 1-3, 6, & 8-10 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of producing 3-hydroxypropionic acid using recombinant microorganism expressing one of the 4 aldehyde dehydrogenases [*ALDH4* (human) or *ALD2* (*S. cerevisiae*) or *aldA* (*E. coli*) or *aldB* (*E. coli*)] with glycerol dehydratase from *Klebsiella pneumoniae* (*dhaB*), does not reasonably provide enablement for combinations of the two genes (encoding aldehyde

dehydrogenase and glycerol dehydratase) from any source, such as from any animal, plant, or microorganism among others. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The scope of the claims does not commensurate with the enablement provided by the disclosure with regard to the extremely large number of aldehyde dehydrogenase and glycerol dehydratase combinations broadly encompassed by the method claims.

While recombinant techniques are known, it is not routine in the art to screen for multiple constructs involving the 2 genes from any source, and further in view of the unpredictability encountered because of the nature of the enzymes and the biosynthetic pathway involving these enzymes which have yielded unstable product (3-HP) as discussed above.

The specification provides insufficient guidance as to which of the 2 gene combinations constructs from the vast numbers be possible choices is likely to be successful in obtaining the desired product.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of the numerous constructs having the desired capability of 3-HP production is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue in using

the modified enzyme in the method claimed. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

5. ***Claim Rejections - 35 USC § 112*** (second paragraph)

Claim 4 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 recites 'ALD2'. The specification on page 6 (line 9) describe 'ALD4' from *S. cerevisiae*. It appears from the specification that 'ALD4' is the correct abbreviation and recitation of 'ALD2' is incorrect, making the claim unclear and indefinite.

6. ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1-3, 6, & 8-10 are rejected under 35 U.S.C. 102(e) as being anticipated by Skraly et al. [USP 6,329, 183, B1]. Skraly et al. teach a method of producing polyhydroxyalkanoates, wherein, diols (glycerol, for example) are provided which can be converted into 3-hydroxypropionate (or 3-HP) from glycerol or glucose, using recombinant reconstructs capable of expressing aldehyde dehydrogenase and glycerol dehydratase [see claims 1-16, especially claims 7-9, 10 & 15-16; abstract; column 1, lines 13-22; column 3, lines 41-49; column 60-67; column 4, lines 1-19; Applicants specification describing the known prior art sequence of *dhaB* gene from *K. pneumonia*]. Since all claim limitations are met as described above or in the cited portions of the reference, Skraly et al. anticipate the claims.

7. Claims 4-5 & 11-12 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

8. Claim 7 is allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tekchand Saidha (Ph.D.) whose telephone number is (703) 305-6595. The examiner can normally be reached on Monday-Friday from 8:15 am to 4:45 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy, can be reached at (703) 308-3804. The fax phone number for this Group in the Technology Center is (703) 308-0294.

Art Unit: 1652

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



**Tekchand Saidha
Primary Examiner, Art Unit 1652
January 5, 2004**